

Response Under 37 CFR §1.116

Expedited Procedure

Examining Group 1645

Application No. 10/590,118

Paper Dated: July 30, 2010

In Reply to USPTO Correspondence of March 31, 2010

Attorney Docket No. 4544-062454

AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims

Claims 1-10 (Cancelled).

Claim 11 (Currently Amended): A diagnostic kit for detecting pulmonary and extra pulmonary tuberculosis, comprising a test card coated with a hydrophobic material, mixing sticks, a glycolipid from a *Mycobacterium tuberculosis* H₃₇RV antigen suspension intercalated or coupled with a liposome surface, a positive control comprising an antibody that binds to a glycolipid ~~said glycolipid~~ from *Mycobacterium tuberculosis*, and a negative control comprising serum antibodies from a subject not previously exposed to *Mycobacterium tuberculosis*.

Claim 12 (Previously Presented): The kit as claimed in claim 11, wherein said antigen suspension is a liposome antigen and said test card is a plastic slide.

Claim 13 (Previously Presented): The kit as claimed in claim 11, wherein said negative control is prepared from the blood of a normal young rabbit.

Claim 14 (Previously Presented): The kit as claimed in claim 11, wherein said positive control is prepared from a 4 to 6 month old rabbit which is immunized with the glycolipid and bled periodically.

Claim 15 (Previously Presented): A method for testing an individual for tuberculosis comprising the steps of applying a positive control, a negative control and a sample to a hydrophobic material, wherein said positive control is an antibody that binds to a glycolipid

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from *Mycobacterium tuberculosis*, and wherein said negative control is a serum antibody from a subject not previously exposed to *Mycobacterium tuberculosis*; adding an antigen suspension to said positive, said negative and said sample; and interpreting a result, wherein clumping of a specific antigen in the suspension and an antibody in the positive control and a test sample from the individual is prognostic for an active tuberculosis infection, and wherein the antigen is a glycolipid antigen from *Mycobacterium tuberculosis* H₃₇Rv (ATCC-27294).

Claim 16 (Previously Presented): The method as claimed in claim 15, wherein said antigen suspension is a liposome antigen.

Claim 17 (Previously Presented): The method as claimed in claim 16, wherein said glycolipid antigen is prepared comprising the steps of:

growing *Mycobacterium tuberculosis* H₃₇Rv (ATCC-27294) strain on Sautons media;

harvesting cells in the media by centrifugation at 4° to 10°C;

subjecting said cells to the step of sonication;

extracting unpurified antigens from said cells;

adding chloroform and methanol mixture (2:1) to said unpurified antigens with stirring at room temperature;

subjecting the mixture to the step of filtration, thereby forming a suspension;

separating said suspension into an upper aqueous phase and a lower organic phase;

removing said upper aqueous phase;

drying said organic phase, thereby forming a solvent containing a lipid; and

purifying the glycolipid antigen.

Claim 18 (Previously Presented): The method as claimed in claim 15, wherein said antigen suspension is prepared comprising the steps of:

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adding a phosphatidylcholine, a cholesterol, a lipid antigen and a dye in a flask, thereby forming a solvent layer;

evaporating said solvent layer, thereby forming dried contents;

dissolving said dried contents in absolute alcohol at 4° to 10°C for 1 to 2 hours to produce said antigen suspension;

adding said antigen suspension to a sucrose solution;

maintaining a temperature of 2° to 8°C overnight;

subjecting said suspension to centrifugation, thereby forming a supernatant and a pellet;

discarding said supernatant; and

suspending said pellet in a buffer.

Claim 19 (Previously Presented): The method as claimed in claim 16, wherein said glycolipid antigen is further purified using column chromatography.

Claim 20 (Previously Presented): The method as claimed in claim 18, wherein said buffer comprises $\text{NaH}_2\text{PO}_4 \cdot 2\text{H}_2\text{O}$, KH_2PO_4 , EDTA, Choline Chloride and Thiomersol.

Claim 21 (Previously Presented): The method as claimed in claim 18, wherein said dye is Sudan black B or Sudan red in chloroform.

Claim 22 (Previously Presented): The method as claimed in claim 15, wherein said anti-mycobacterial glycolipid antibody is isolated from a rabbit immunized against the glycolipid antigen from *Mycobacterium tuberculosis* H₃₇Rv.

Claim 23 (Previously Presented): The method as claimed in claim 15, wherein said antibodies from a subject not previously exposed to *Mycobacterium tuberculosis* are isolated from a rabbit that has not been exposed to *Mycobacterium tuberculosis*.

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Claim 24 (Previously Presented): The method as claimed in claim 15, wherein said anti-mycobacterial glycolipid antibody is coupled onto a surface of a liposome.

Claim 25 (Previously Presented): The method as claimed in claim 23, wherein said rabbit was immunized against a heat inactivated sonicated *Mycobacterium tuberculosis* H₃₇Rv strain.